

REMARKS

Favorable reconsideration of the present application is respectfully requested.

Claims 1-21 are currently pending in the application.

Claims 1, 5, 7-9 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3,786,812 to Neeffe ("Neeffe"), Ding (PSTT, Vol. 1, No. 8, Nov. 1998) ("Ding"), Nagarsenker et al. (Int. Journal of Pharmaceutics 190 (1999) 63-71) ("Nagarsenker") and EP Publication No. 0 480 690 to Evitts et al. ("Evitts").

Claims 4, 10-12 and 14-15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Neeffe, Ding, Nagarsenker and Evitts, and further in view of U.S. Patent No.

5,891,932 to Benz et al. ("Benz") and U.S. Patent No. 4,925,017 to Jessen ("Jessen").

Claims 6 and 17-19 were rejected under 35 U.S.C. 103(a) as being unpatentable over Neeffe, Ding, Nagarsenker and Evitts, and further in view of U.S. Patent No. 6,264,971 to Darouger et al. ("Darouger"). Claims 6 and 16 were rejected under 35 U.S.C. 103(a) as being unpatentable over Neeffe, Ding, Nagarsenker and Evitts, and further in view of U.S. Patent No. 4,052,505 to Higuchi et al. ("Higuchi"). Claims 2-3, 13 and 21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Neeffe, Ding, Nagarsenker and Evitts, and further in view of Seijo et al. (Int. Journal of Pharmaceutics Vol 62, Issue 1, 15 July 1990, abs) ("Seijo").

Without acceding to the outstanding rejections, independent Claim 1 has been amended to incorporate certain distinguishing features of Applicants' invention previously addressed in Claim 3 (now amended accordingly). As amended, Claim 1 recites, *inter alia*, a drug delivery system including a contact lens having dispersed therein as nanoparticles an ophthalmic drug nanoencapsulated with an encapsulation material, where said nanoparticles are dispersed within the contact lens in an amount such

that the contact lens remains optically transparent, where optically transparent is a degree of transparency equal to that of p-HEMA or other material employed as a contact lens.

The applied references neither disclose nor suggest a drug delivery system having the features presently recited in Claim 1. As acknowledged on page 5 of the Office Action, Neeffe and Benz are silent to the phrase “optically transparent.” Indeed, the presence of drugs in the outer peripheral portion of the Neeffe contact lens renders that portion of the lens translucent or opaque (See, e.g., Figs. 3-4 and column 3, lines 27-30). The secondary references fail to supply this deficiency. Benz, for example, discloses the use of p-HEMA as a material in a contact lens, but does not disclose or suggest maintaining optical transparency in a lens having nanoparticles dispersed therein. Further, Benz teaches the use of other materials in lieu of p-HEMA in order to obtain improved internal water retention in the contact lens (See, e.g., column 2, lines 16-18).

The Office asserts on page 8 of the Office Action that it would have been obvious to one of skill in the art determine an amount of nanoparticles and to distribute the nanoparticles in such a manner that optical transparency is maintained.

Applicants respectfully submit that such an assertion is improper because the Office Action relies on information gleaned solely from Applicants’ disclosure. MPEP § 2142 states that “impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art” (emphasis added by Applicants). “Any judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant’s disclosure, such a reconstruction is proper” (see, *In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971),

(emphasis added by Applicants)). However, in the present invention, Applicants believes that such a reconstruction is not proper. The references on which the rejections are based do not suggest determining an amount of nanoparticles and dispersing the nanoparticles in a contact lens in such a manner that optical transparency in the lens is maintained. The advantages of maintaining optical transparency in a contact lens having an ophthalmic drug dispersed therein as nanoparticles are apparent. Yet, the applied references neither disclose nor suggest determining an amount of nanoparticles and dispersing the nanoparticles in a contact lens in such a manner that optical transparency in the lens is maintained. It is, therefore, not seen that one of ordinary skill in the art, without the benefit of Applicants' disclosure, would look to determine an amount of nanoparticles and distribute the nanoparticles in such a manner that optical transparency is maintained.

Accordingly, Claim 1, at least as presently amended, distinguishes patentably over the applied references and should therefore be allowed. Dependent Claims 2-21 should also be allowed, at least in view of their dependence from Claim 1 as well as for the additional subject matter recited in the dependent claims. Claim 21 has been amended for conformance with Claim 1.

A Notice of Allowance is respectfully requested.

Should the Examiner believe that any further action is necessary to place this application in better form for allowance, the Examiner is invited to contact Applicants' representative at the telephone number listed below.

The Commissioner is hereby authorized to charge to Deposit Account No. 50-1165 (T2315-908542US02) any fees under 37 C.F.R. §§ 1.16 and 1.17 that may be required by this paper and to credit any overpayment to that Account. If any extension of

time is required in connection with the filing of this paper and has not been separately requested, such extension is hereby requested.

Respectfully submitted,

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